In view of the above amendments and following remarks, reconsideration and allowance of the application is hereby respectfully requested.

REMARKS

In the Amendment filed on June 19, 2002, and in response to the restriction requirement under 35 U.S.C. § 121, Group I (claims 1-19) were canceled without prejudice. Claims 36-48 were added in the Supplemental Amendment filed on August 1, 2002. Claims 21 and 37 are being canceled without prejudice herein. Thus, claims 20, 22-35, 36, and 38-48 are pending in the application for examination on the merits along with newly added claims 49-64.

Independent claim 20 was previously amended consistent with the Examiner's suggestion during the interview to change the term "comprised" to "consisting essentially" to overcome the 35 U.S.C. § 103(a) art rejection over US Patent No. 5,635,204 to Gevirtz et al.. Applicant hereby acknowledges the *withdrawal* of this rejection by the Examiner in the Office Action dated August 20, 2002.

Independent claim 20 has been amended herein to include the limitations of dependent claim 21, namely that the guanidine derivative is selected from the group consisting of guanabenz, guanabenz acetate, guanoxabenz, clonidine, guanacline, guanadrel, guanazodine, guanethidine, guanfacine and guanochlor, guanoxan and chlonidine. For the reasons set forth below, this amendment is believed to overcome the Examiner's new ground of rejection under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 4,060,640 to Kodama et al.

For the reasons set forth below, Applicant has also amended independent claim 36 to include the limitations of dependent claim 37, namely that the guanidine derivative is selected from the group consisting of guanabenz, guanabenz acetate, guanoxabenz, clonidine, guanacline, guanadrel, guanazodine, guanethidine, guanfacine and guanochlor, guanoxan and chlonidine.

Claim 38 has been amended herein to overcome the Examiner's rejection of claim 38 under 35 U.S.C. §112, second paragraph. The claim has been amended consistent with the Examiner's suggested amendment set forth on page 2 of the Office Action dated August 20, 2002 and the amendment is believed to overcome the rejection. Withdrawal of the rejection of claim 38 under 35 U.S.C. §112, second paragraph is believed to be warranted.

New claims 49-64 are being added to more clearly and distinctly claim Applicant's invention. In particular, new claims 49-64 are directed to a method for providing *chemical restraint* of an animal, comprising administering to the animal a pharmaceutically effective amount of a composition comprised of a guanidine derivative. Support for the newly added claims can be found throughout the Specification, *e.g.*, at page 7, lines 12-17; page 10, lines 4-9; and page 19, lines 1-5. Thus, no new matter is being added by the amendment.

A "VERSION WITH MARKINGS MADE TO SHOW CHANGES" (page 14) and an "AMENDED VERSION WITHOUT MARKINGS" (pages 15-18) of amended claims 20, 36, 38 and newly added claims 49-64 is being submitted concurrently herewith.

Rejection Under 35 U.S.C. § 103(a)

Asset forth above, in view of Applicant's amemdment filed on August 1, 2002, the rejection of claims 20-35 under 35 U.S.C. § 103(a) has been withdrawn by the Examiner (*see*, page 3 of the Office Action dated August 20, 2002).

Newly added claims 49-64 are believed to be free of art and are believed to be in condition for allowance. None of the art of record teaches or suggests a method for

providing *chemical restraint* of an animal, comprising administering to the animal a pharmaceutically effective amount of a composition comprised of a guanidine derivative.

Claims 36-48 stand rejected under 35 U.S.C. § 103(a) as being obvious over US Patent No. 5,635,204. Applicant respectfully traverses the rejection. U.S. Patent No. 5,635,204 is directed to the use of a *required combination* of drugs to induce *general anesthesia* or a surgical stage of anesthesia in a recumbent individual. The specification of the '204 patent at column 2, lines 9-23 specifically recites the required combination of drugs for induction of *general anesthesia*, namely fentanyl or a fentanyl analog (line 12); an α_2-adrenergic agonist such as clonidine (lines 13-16); and an amnesia inducing drug such as ketammine (lines 17-19).

With respect to claims 36-48, there is absolutely no teaching or suggestion anywhere in the '204 patent of a method of rapid induction of long lasting sedation and analgesia in a standing equine animal (*e.g.*, a horse) via administration of a single guanidine derivative as set forth in independent claim 36. The use of a single guanidine derivative selected from the group set forth in amended claim 36 in a *standing equine* animal cannot be obvious based upon the teachings of the '204 patent.

General or surgical anesthesia places an animal in recumbancy and increases the

risk to the patient and, as set forth in the '204 patent, *requires* administration of additional drugs, namely narcotics and dissociative anesthetic agents such as fentanyl and ketamine respectively, which increase the risk of adverse reactions in the patient. The methods of claims 36-48 do not require administration of any agent other than a guanidine derivative for induction of the desired sedation and analgesia. The induction of the desired sedation and analgesia *in a standing equine animal* and cannot be obvious in view of the teachings of the '204 patent. Therefore, withdrawal of the rejection of claims 36-48 under § 103(a) is believed to be warranted and is respectfully requested.

Likewise, with respect to newly added claims 49-64, as demonstrated in Applicant's video, a single administration of a guanidine derivative produced profound sedation and analgesia and an effective means of a rapidly reversible *chemical restraint* in animals, especially large animals, *e.g.*, horses. There is absolutely no teaching or suggestion anywhere in the '204 patent of a method for providing for chemical restraint of animals.

Claims 20-48 stand rejected as being unpatentable over US Patent No. 4,060,640 to Kodama et al. In particular, the Examiner states that Kodama et al. "disclose a method of inducing sedation in mammals using the instant guanidine derivatives." Applicant disagrees. The o-halobenzylidenaminoguanidines disclosed in Kodama et al. do not read

on the guanidine derivatives of Applicant's invention. In fact none of the guanidine derivatives set forth in applicants disclosure are taught or suggested in Kodama et al. Certainly none of the guanidine derivatives of amended claims 20 and 36 are taught or suggested by Kodama et al. Thus, the methods set forth in Applicant's amended claims cannot be obvious in view of Kodama et al.

With respect to newly added claims 49-64, Kodama et al. certainly does not teach or suggest a method for providing chemical restraint in an animal. In fact, there is no teaching or suggestion in any art of record for a method for providing chemical restraint of an animal, comprising administering to the animal a pharmaceutically effective amount of a composition comprised of a guanidine derivative

Accordingly, in view of the amendment of claims 20 and 36 and the remarks set forth above, withdrawal of the rejection of claims 20-48 under 35 U.S.C. § 103(a) is believed to be warranted and is earnestly solicited. Likewise, for the reasons set forth above, newly added claims 36-48 are also believed to be in condition for allowance.

Related Matters

The Examiner's objection to Tables 1-3 in the specification is noted. Applicant

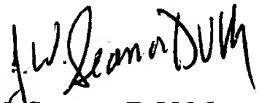
will amend the specification to include a "Brief Description of the Drawings" and submit Tables 1-3 as Drawings as requested by the Examiner upon receipt of a Notice of Allowability of the claims.

A courtesy copy of this amendment ant the RCE request is also being faxed to the Examiner at (703) 746-5317.

The fee for a three month extension of time and the filing fee for the RCE are being submitted concurrently herewith. No additional fee is believed to be due, however, the Commissioner is hereby authorized to debit or credit deposit account number 11-0978 for any additional fees deemed to be due or issue a credit for any overpayment thereof. The Examiner is encouraged to contact the undersigned attorney directly if such contact will enhance the efficient prosecution of the application to issue.

Respectfully submitted,

KING AND SCHICKLI, PLLC



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Certificate of Facsimile Transmission

I hereby certify that this correspondence is being transmitted by facsimile to: Assistant Commissioner for Patents, Washington, D.C. 20231, to telephone number **(703) 746-5317** on:

February 20, 2003
Date

Carolina Perdomo
By

VERSION WITH MARKINGS MADE TO SHOW CHANGES

20. (Twice Amended) A method of inducing rapid onset and long lasting sedation and analgesia in an animal, comprising administering to the animal a pharmaceutically effective amount of a composition consisting essentially of a guanidine derivative selected from the group consisting of guanabenz, guanabenz acetate, guanoxabenz, clonidine, guanacline, guanadrel, guanazodine, guanethidine, guanfacine and guanochlor, guanoxan and chlonidine.

36. (Amended) A method of inducing rapid onset and long lasting sedation and analgesia in a standing equine animal, comprising administering to the animal a pharmaceutically effective amount of a composition comprised of a guanidine derivative selected from the group consisting of guanabenz, guanabenz acetate, guanoxabenz, clonidine, guanacline, guanadrel, guanazodine, guanethidine, guanfacine and guanochlor, guanoxan and chlonidine.

38. (Amended) The method of claim 36, wherein the guanadine derivative is guanabenz acetate or a pharmaceutically acceptable derivative ~~derivatives~~ thereof.